

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON**

LEIGH BROOKE GOLDBERG and ADAM MATHEW BAEST,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.; TEVA WOMEN'S HEALTH, INC. d/b/a TEVA WOMEN'S HEALTH, LLC; TEVA WOMEN'S HEALTH, LLC; TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC; THE COOPER COMPANIES, INC.; and COOPERSURGICAL, INC.,

Defendants.

Case No.: 2:21-cv-00586

JURY TRIAL DEMANDED

COMPLAINT FOR DAMAGES

COME NOW Plaintiffs Leigh Brooke Goldberg and Adam Mathew Balest, by and through their counsel, and file this Complaint against Defendants Teva Pharmaceuticals USA, Inc.; Teva Women's Health, Inc., doing business as Teva Women's Health, LLC; Teva Women's Health, LLC; The Cooper Companies, Inc.; and CooperSurgical, Inc. (collectively hereinafter "Defendants"), both jointly and severally, as the companies and/or successors in interest to the companies that designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, and/or sold ParaGard Intrauterine medical device that was implanted into Plaintiff, and throughout the United States. Accordingly, Plaintiff alleges and states as follows:

I. INTRODUCTION

1. This is an action for damages relating to Defendants' design, manufacture, surveillance, sale, marketing, advertising, promotion, labeling, packaging, and distribution of ParaGard Intrauterine medical device (hereinafter "ParaGard IUD").

2. ParaGard IUD is an intrauterine device, however, it is regulated as a drug. It is placed into the uterus to prevent conception.

3. ParaGard IUD has a propensity to break at the arms upon explant resulting in serious injuries.

4. Plaintiff used ParaGard IUD, and as a result of its use suffered injuries.

II. GENERAL ALLEGATIONS

5. Plaintiff Leigh Brooke Goldberg (“Plaintiff”), by and through Plaintiff’s attorneys The Ledger Law Firm brings this action for personal injuries suffered as a result of using the defective and dangerous ParaGard IUD.

6. ParaGard IUD is prescribed to prevent conception, and at all times relevant hereto, was manufactured, designed, tested, packaged, labeled, marketed, advertised, promoted, distributed, and sold by Defendants. On information and belief, Plaintiff used ParaGard IUD resulting in injuries.

III. PARTIES

7. Plaintiff Leigh Brooke Goldberg is an individual, and was a citizen and resident of the State of Colorado at the time of her ParaGard IUD implant. At the time of her breakage and removals, she was a citizen and resident of Washington and remains same as of this filing. Plaintiff Adam Mathew Balest is an individual and citizen of Washington and is married to Plaintiff Leigh Brooke Goldberg. All references herein to “Plaintiff” without specification as to name pertains to Plaintiff Leigh Brooke Goldberg.

8. Plaintiff was implanted with ParaGard IUD in 2009. It was removed in 2019, resulting in injuries.

9. Defendant Teva Pharmaceuticals USA, Inc. (hereinafter “Teva USA”) is a Delaware corporation with its principal place of business in Parsippany, New Jersey. At times relevant to this action, Teva USA designed, developed, manufactured, and marketed ParaGard IUD at issue. At times relevant to this action, Teva USA communicated with the United States Department of Health and Human Services, Food and Drug Administration (hereinafter “FDA”) regarding the sale, use, and safety concerns related to ParaGard IUD, which includes managing product recalls, investigating adverse events from ParaGard IUD users, and performing mandatory reporting to the FDA regarding ParaGard IUD.

10. At times relevant to this action, Teva USA was involved in regulatory communications and medical communications, including but not limited to communications with physicians, doctors, the FDA, and other medical personnel, which led to activities giving rise to failure to warn, negligence, gross negligence, common law fraud, negligent misrepresentation, breach of warranty, and violation of consumer protection laws.

11. Defendant Teva Women's Health, Inc., is a Delaware corporation with its principal place of business located at 425 Privet Rd., in Horsham, Pennsylvania and is and/or was a wholly owned subsidiary of Teva USA, and/or operated as a successor in interest to Duramed Pharmaceuticals, Inc., a division of Barr Pharmaceuticals, Inc., and/or assumed Duramed Pharmaceuticals, Inc., a division of Barr Pharmaceuticals, Inc., in a name change after its acquisition by Teva USA. Teva Women's Health, Inc., converted into Teva Women's Health, LLC in 2017 and continues to operate as Teva Women's Health, LLC. At times relevant to this action, Teva Women's Health, Inc., designed, developed, manufactured, and marketed ParaGard IUD at issue.

12. Defendant Teva Women's Health, LLC is a Delaware limited liability company with its principal place of business located at 425 Privet Rd., in Horsham, Pennsylvania and is and/or was a wholly owned subsidiary of Defendant Teva USA. Teva Women's Health's sole member is Barr Pharmaceuticals, LLC, formed under Delaware law with its principal place of business in New Jersey, and the sole member of Barr Pharmaceuticals, LLC, is Teva USA. For diversity purposes, Teva Women's Health, LLC, is a citizen of Delaware and New Jersey. Teva Women's Health, LLC is the product of an entity conversion pursuant to DEL. CODE ANN. tit. 8, § 266. Teva Women's Health, Inc., converted into Teva Women's Health, LLC and continues to operate as a limited liability company instead of a corporation (Teva Women's Health, LLC formerly known as Teva Women's Health, Inc. collectively hereinafter "Teva Women's Health").

13. Accordingly, Duramed Pharmaceuticals, Inc., a division of Barr Pharmaceuticals, Inc., d/b/a Teva Women's Health, Inc., (hereinafter "Duramed"), acquired FEI Women's Health in 2005 wherein the asset of ParaGard IUD was acquired in the deal. Duramed was acquired by

Teva USA in 2008 wherein its name was changed to Teva Women’s Health, Inc., a wholly owned subsidiary of Teva USA.

14. Defendant Teva Branded Pharmaceuticals Products R&D, Inc. (“Teva R&D”) is a corporation with its principal place of business located at 41 Moores Rd. in Frazer, Pennsylvania (collectively Defendants Teva USA, Teva Women’s Health and Teva R&D are referred to herein as the “Teva Defendants”). At all times relevant to this action, Teva R&D designed, developed, manufactured, and marketed the Paragard at issue. At times relevant to this action, Teva R&D communicated with the FDA regarding the sale, use, and safety concerns related to ParaGard IUD.

15. Defendant The Cooper Companies, Inc., (hereinafter “Cooper Companies”) is a Delaware corporation with its principal place of business located at 6140 Stoneridge Mall Rd., in Pleasanton, California. Cooper Companies purchased assets and global rights and business of ParaGard IUD in September 2017 for \$1.1 Billion, including their manufacturing facility in Buffalo, New York.

16. Defendant CooperSurgical, Inc., (hereinafter “CooperSurgical”) is a Delaware corporation with its principal place of business located at 95 Corporate Dr. in Trumbull, Connecticut and a subsidiary of Defendant Cooper Companies (Defendants Cooper Companies and CooperSurgical collectively hereinafter “Cooper Defendants”).

17. At all times relevant hereto and alleged herein, Defendants conducted and continue to conduct substantial business within the state of Washington, and within the Western District of Washington.

18. At times relevant hereto and alleged herein, Defendants conducted and continue to regularly conduct substantial business within the state of Washington, which included and continues to include the research, safety surveillance, manufacture, sale, distribution, and marketing of ParaGard IUD, which is distributed through the stream of interstate commerce into the state of Washington, and within the Western District of Washington.

19. At all relevant times, each Defendant acted in all aspects as the agent and alter ego of each other.

20. Cooper Defendants are liable as successors in interest under any other state or federal successor-in-interest acts or statutes, and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

21. Upon reasonable belief, Duramed became Teva Women's Health, Inc., through a name change in 2008. Teva Women's Health, Inc., then became Teva Women's Health, LLC through a conversion in 2017. Teva Women's Health, LLC then sold all of its assets including ParaGard IUD to Cooper Defendants in 2017. Teva Women's Health, LLC became a *holdings* company with no tangible assets.

22. Cooper Defendants knew or should have known that the transfer and conversion of Teva Women's Health, Inc., was intended to thwart potential creditors from having a claim against Teva Women's Heath, Inc. or Teva Women's Health, LLC. Therefore, Cooper Defendants are liable pursuant to the Federal Consumer Protection Acts and are also liable as successors-in-interest under any other state or federal successor interest acts or statutes.

23. The liability of these companies has passed on through various business instruments and now lies with both the Teva Defendants and the Cooper Defendants.

24. At times relevant and material hereto, Defendants were engaged in the business of, or were successors in interest to entities engaged in the business of, researching, developing, designing, formulating, licensing, manufacturing, testing, producing, processing, assembling, packaging, inspecting, distributing, selling, labeling, monitoring, marketing, promoting, advertising, and/or introducing into interstate commerce throughout the United States, and in the state of Washington, and within the Western District of Washington, either directly or indirectly, through third parties, subsidiaries, and/or related entities, ParaGard IUD, a drug used in the prevention of pregnancy, implanted in patients throughout the United States, including Plaintiff.

25. At all times alleged herein, Defendants were authorized to conduct or engage in business within the state of Washington and supplied ParaGard IUD within the state of Washington and the Western District of Washington. Defendants received financial benefit and profits as a result of designing, manufacturing, marketing, advertising, selling, and distributing ParaGard IUD within the state of Washington, and the Western District of Washington.

26. The combined acts and/or omissions of each Defendant resulted in indivisible injuries to Plaintiff. Each of the above-named Defendants is a joint tortfeasor and/or co-conspirator and is jointly and severally liable to Plaintiff for the negligent acts and omissions alleged herein. Each of the above-named Defendants directed, authorized, or ratified the conduct of each and every other Defendant.

27. The amount in controversy exceeds the jurisdictional limits of this court.

IV. JURISDICTION AND VENUE

28. Plaintiff incorporates by reference all of the above paragraphs.

29. Jurisdiction is proper in this court pursuant to 28 U.S.C. § 1332 as complete diversity of citizenship exists between Plaintiff and Defendants and the matter in controversy exceeds the sum of \$75,000.00, exclusive of interest and costs.

30. This Court has jurisdiction over the non-resident Defendants because they have conducted business in the state of Washington. Defendants have committed a tort in whole or in part in the state of Washington and have regular and continuing contacts with Washington.

31. In addition, venue of this case is proper in the state of Washington pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff's claims occurred in the state of Washington.

V. FACTUAL ALLEGATIONS

32. ParaGard IUD is an intrauterine drug that can provide long term birth control, up to 10 years, without hormones.

33. ParaGard IUD is a T-shaped plastic frame made of polyethylene and barium sulfate that is inserted into the uterus. Copper wire coiled around the IUD produces an inflammatory reaction that is toxic to sperm and egg. A monofilament polyethylene thread is tied through the tip, resulting in two white threads, which aid in the detection and removal of the drug.

34. ParaGard IUD has a propensity to break at the arms upon explant resulting in serious injuries.

35. At relevant times, Teva Defendants designed, researched, manufactured, labeled, packaged, promoted, marketed, and/or sold ParaGard IUD at issue after receiving New Drug Application approval from the FDA.

36. In 2008, Teva USA became the owner of ParaGard IUD when it acquired Duramed Pharmaceuticals, Inc., a division of Barr Pharmaceuticals, Inc., through its purchase of Barr Pharmaceuticals, Inc.

37. Upon information and belief, when Teva USA acquired Duramed, a division of Barr Pharmaceuticals, Inc., it also acquired Duramed's manufacturing facilities, sales force, and responsibility for maintaining and updating the labeling for ParaGard IUD.

38. Shortly thereafter, Teva USA changed the name of Duramed Pharmaceuticals, Inc., a division of Barr Pharmaceuticals, Inc., to Teva Women's Health, Inc., a wholly owned subsidiary of Teva USA.

39. On August 31, 2009, Duramed Pharmaceuticals, Inc., filed with the Ohio Secretary of State a Certificate of Amendment to Foreign Corporation Application for License requesting a name change. A new entity was not created and no entities were dissolved. Duramed's license number did not change. Instead, Duramed changed its name to Teva Women's Health, Inc.

40. Upon information and belief, Teva Women's Health, Inc., is simply a new name for Duramed.

41. Upon information and belief, and for purposes of liability and interest, Teva Women's Health, Inc., is the same entity as Teva Women's Health, LLC. Teva Women's Health, Inc., converted into Teva Women's Health, LLC under the laws of Delaware. DEL. CODE ANN. tit. 8, § 266. Pursuant to DEL. CODE ANN. tit. 8, § 266, a company that converts from one entity into another is deemed to be a continuation of the preexisting company. A conversion does not equate to a dissolution and no winding up takes place. Therefore, Teva Women's Health, Inc., did not dissolve, windup, or *cease to exist* and liability continues from the corporation to the limited liability company.

42. Upon information and belief on August 11, 2017, Teva Women's Health, Inc., converted into Teva Women's Heath, LLC and sold all of its assets.

43. On September 11, 2017, Teva Defendants sold ParaGard IUD to Cooper Defendants.

44. ParaGard IUD is currently sold only in the United States and had earned revenues of approximately \$168 million for the twelve-month period ending June 30, 2017.

45. Cooper Defendants still manufacture and sell ParaGard IUD in the United States.

46. ParaGard IUD was marketed heavily by Defendants as being safe and effective, and promising fewer side effects than other birth control methods.

47. The marketing and promotional efforts of Defendants, their advertisers, and sales force served to overstate the benefits of ParaGard IUD and minimize and downplay the risks. These promotional efforts were made while Defendants fraudulently withheld important safety information from healthcare providers and the public.

48. Prior to Plaintiff being implanted with ParaGard IUD, Defendants knew or should have known that the drug was defective and unreasonably dangerous.

49. Defendants knew or should have known that ParaGard IUD can and does cause serious harm to individuals who use it, due to the risk of ParaGard IUD's arm breaking upon removal.

50. Defendants knew of these risks from the trials they performed, their post-marketing experience and complaints, third-party studies, and their own analysis of these studies, but took no action to adequately warn or remedy the defects and instead concealed, suppressed, and failed to disclose or fix this danger.

51. The product warnings for ParaGard IUD were vague, incomplete, or otherwise wholly inadequate to alert prescribing physicians and patients to the actual risks associated with ParaGard IUD.

52. Defendants' marketing and promotion, through its own website, sought to reassure physicians and patients of Defendants' alleged longstanding record of quality and safety assurance.

53. Based on these representations, upon which Plaintiff and her physician relied, Plaintiff had ParaGard IUD implanted, believing it would be safe and effective for the entire duration it was implanted and upon removal.

54. Since 2010, the FDA has received over 1600 reports of ParaGard IUD breakage, with over 700 classified as serious.

55. Defendants' failure to adequately communicate and report to the FDA the injuries associated with ParaGard IUD resulted in inadequate warnings.

56. Cooper Defendants are also liable as successors in interest under any other state or federal successor-in-interest acts or statutes, and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

VI. PLAINTIFF'S USE OF PARAGARD IUD

57. On information and belief, in 2009, Plaintiff was implanted with Defendants' ParaGard IUD by a physician.

58. Plaintiff, a healthy woman, wanted a ParaGard IUD because it was a reversible form of birth control that would allow her to conceive in the future.

59. On or about April 4, 2019, Plaintiff went to have the ParaGard IUD removed in Washington. An ultrasound of the pelvis revealed that the ParaGard IUD was missing an arm.

60. Plaintiff's healthcare provider attempted to remove the ParaGard IUD as instructed by Defendants, by grasping the ParaGard IUD and pulling gently. Despite following the instructions provided by Defendants, only a portion of the ParaGard IUD was retrieved with one arm missing.

61. On or about June 13, 2019, Plaintiff's physician removed the ParaGard IUD arm via hysteroscopy under general anesthesia.

62. Prior to her procedures, Plaintiff and her doctors were provided with no warning from Defendants of the risk of ParaGard IUD failure and injury, nor were Plaintiff and her doctors provided with adequate warning of the risk of removal of ParaGard IUD. This information was known or knowable to Defendants.

63. On information and belief, Plaintiff used the ParaGard IUD manufactured, packaged, marketed, sold, and/or distributed by Defendants. The ParaGard IUD reached Plaintiff without substantial change in the drug's condition.

64. On information and belief, as a direct and proximate result of using ParaGard IUD, Plaintiff developed serious and/or permanent adverse effects.

65. As a result of said adverse effects, Plaintiff suffered significant bodily and mental injuries, pain and suffering, mental anguish, disfigurement, embarrassment, inconvenience, loss of earnings and earning capacity, and have and will incur past and future medical expenses.

66. At all relevant times, each Defendant had knowledge that there was a significant increased risk of adverse events associated with ParaGard IUD including arm breakage, and despite this knowledge Defendants continued to manufacture, market, distribute, sell, and profit from sales of ParaGard IUD.

67. Cooper Defendants continue to manufacture, market, distribute, sell, and profit from sales of ParaGard IUD.

68. Despite such knowledge, Defendants knowingly, purposely, and deliberately failed to adequately warn Plaintiff, patients, consumers, medical providers, and the public of the increased risk of serious injury associated with using ParaGard IUD.

69. On information and belief, Plaintiff's prescribing physicians would not have prescribed ParaGard IUD to Plaintiff, would have changed the way they warned Plaintiff about the signs and symptoms of serious adverse effects of ParaGard IUD, and discussed with Plaintiff the true risks of arm breakage and resulting injuries and complications had Defendants provided said physicians with an appropriate and adequate warning regarding the risks associated with the use of ParaGard IUD.

70. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injuries, including, but not limited to, pain, suffering, and loss of reproductive health, which resulted in damages to Plaintiff in a sum in excess of the jurisdictional limits of the Court.

71. Defendants maintained a duty to Plaintiff after the ParaGard IUD was implanted and until it was removed.

72. Cooper Defendants are also liable as successors in interest under any other state or federal successor-in-interest acts or statutes, and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

73. As a direct result of Plaintiff's use of ParaGard IUD, Plaintiff suffered from having a broken arm of the ParaGard IUD in her, causing her damage, including but not limited to pain, suffering, mental anguish, the loss of reproductive health, loss of enjoyment of life, medical expenses and other out-of-pocket losses, and loss of income.

VII. DELAYED DISCOVERY

74. Plaintiff incorporates by reference the factual portion of this Complaint as if fully set forth herein and additionally, or in the alternative, if same be necessary, alleges as follows:

75. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiff had been injured, the cause of the injury and the tortious nature of the wrongdoing that caused the injury.

76. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages and their relation to Plaintiff's ParaGard IUD and Defendants' wrongful conduct was not discovered and could not have been discovered until a date within the applicable statute of limitations for filing each of Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

77. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of material facts known by Defendants when they had a duty to disclose those facts. Defendants' purposeful and fraudulent acts of concealment have kept Plaintiff ignorant of vital information essential to the pursuit of Plaintiff's claims, without any fault or lack of diligence on Plaintiff's part, for the purpose of obtaining delay on Plaintiff's filing of her causes of action. Defendants' fraudulent concealment did result in such delay.

78. Defendants are estopped from relying on the statute-of-limitations defense because Defendants failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of their ParaGard IUD.

VIII. CAUSES OF ACTION

COUNT I – NEGLIGENCE

79. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

80. At times relevant, Defendants were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and/or distributing ParaGard IUD, including the one that was implanted into Plaintiff.

81. Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, safety surveillance, and distribution of ParaGard IUD so as to avoid exposing others to foreseeable and unreasonable risks of harm.

82. Defendants breached their duty of care to Plaintiff and her physicians in the manufacture, design, labeling, warnings, instructions, sale, marketing, safety surveillance, and distribution of ParaGard IUD.

83. Defendants knew that ParaGard IUD could break upon removal and failed to warn Plaintiff of this potential injury.

84. Defendants had a duty to warn Plaintiff, Plaintiff's physician, and/or the medical community of the potential for breakage at the arm(s) upon removal.

85. Cooper Defendants had a continuing duty to warn Plaintiff, Plaintiff's physician, and/or the medical community of the potential for breakage at the arm(s) upon removal upon their acquisition of ParaGard IUD in September 2017.

86. Defendants knew or reasonably should have known that ParaGard IUD was dangerous or likely to be dangerous when used in its intended or reasonably foreseeable manner.

87. At the time of the manufacture and sale of ParaGard IUD, Teva Defendants knew or should have known that ParaGard IUD was designed and manufactured in such a manner as to present an unreasonable risk of the fracture of the arm of the drug upon removal.

88. At the time of the manufacturer and sale of ParaGard IUD, Teva Defendants knew or should have known that ParaGard IUD was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement and subsequent removal.

89. At the time of the manufacture and sale of ParaGard IUD, Teva Defendants knew or should have known that using ParaGard IUD for its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe injuries, including but not limited to additional surgeries and/or medical procedures in order to remove the fragmented drug, even leading to hysterectomy.

90. Upon acquisition of ParaGard IUD from Teva Defendants, Cooper Defendants are charged with the same knowledge that Teva Defendants knew or should have known regarding the risks associated with ParaGard IUD at the time of manufacture and sale, and therefore, all Defendants had a continuing duty to warn Plaintiff and her physicians or the general healthcare community of those reasonably known risks.

91. Defendants knew or reasonably should have known that the consumers of ParaGard IUD would not realize the danger associated with using the drug for its intended use and/or in a reasonably foreseeable manner.

92. Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution, and sale of ParaGard IUD in, among others, the following ways:

- a. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking measures to reduce or avoid harm;
- b. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other drugs available for the same purpose;
- c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications;
- d. Failing to use reasonable care to warn or instruct Plaintiff, Plaintiff's healthcare providers, or the general healthcare community about ParaGard IUD's substantially dangerous condition or about facts making the product likely to be dangerous, including pre- and post-sale;
- e. Failing to perform reasonable pre- and post-market testing of ParaGard IUD to determine whether the product was safe for its intended use;
- f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would recommend, use, implant, and remove ParaGard IUD;
- g. Advertising, marketing, and recommending the use of ParaGard IUD, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with and inherent in the use of ParaGard IUD;
- h. Representing that ParaGard IUD was safe for its intended use when, in fact, Defendants knew and should have known the product was not safe for its intended purpose;

- i. Continuing manufacture and sale of ParaGard IUD with the knowledge that the IUD was dangerous and not reasonably safe, and failing to comply with the FDA's good-manufacturing regulations;
- j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of ParaGard IUD so as to avoid the risk of serious harm associated with the use of the drug;
- k. Failing to establish an adequate quality-assurance program used in the manufacturing of ParaGard IUD;
- l. Failing to establish and maintain an adequate post-marketing surveillance program for ParaGard IUD;
- m. Failing to adequately and correctly report safety information relative to ParaGard IUD product resulting in inadequate warnings; and
- n. Failing to provide adequate and continuous warnings about the inherent danger of breakage with ParaGard IUD upon removal.

93. A reasonable manufacturer, distributor, and/or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

94. As a proximate result of Defendants' design, manufacture, marketing, sale, and/or distribution of ParaGard IUD, Plaintiff has been injured

95. and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, loss of comfort, and economic damages.

96. Cooper Defendants are also liable as successors in interest under any other state or federal successor-in-interest acts or statutes, and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory damages, punitive damages, and costs in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT II – STRICT LIABILITY DESIGN DEFECT

97. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

98. ParaGard IUD is inherently dangerous and defective, unfit and unsafe for its intended use and reasonably foreseeable uses and does not meet or perform to the expectations of patients and their healthcare providers.

99. ParaGard IUD was expected to, and did, reach its intended consumer without substantial change in the condition in which it was in when it left Defendants' possession.

100. The ParaGard IUD implanted in Plaintiff was defective in design because it failed to perform as safely as persons who ordinarily use the products would have expected at time of use.

101. The ParaGard IUD implanted in Plaintiff was defective in design, in that the IUD's risks of harm exceeded its claimed benefits.

102. Plaintiff and her healthcare providers used ParaGard IUD in a manner that was reasonably foreseeable to Defendants.

103. Neither Plaintiff nor her healthcare providers could have by the exercise of reasonable care discovered the IUD's defective conditions or perceived its unreasonable dangers prior to implantation of the drug.

104. As a result of the foregoing design defects, ParaGard IUD created risks to the health and safety of its users that were far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of ParaGard IUD.

105. Defendants have intentionally and recklessly designed ParaGard IUD with wanton and willful disregard for the rights and health of Plaintiff and others, and with malice, placing their economic interests above the health and safety of Plaintiff and others.

106. As a proximate result of Defendants' design of ParaGard IUD, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages.

107. Cooper Defendants are also liable as successors in interest under any other state or federal successor in interest acts or statutes, and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory damages, punitive damages, and costs in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT III – STRICT LIABILITY MANUFACTURING DEFECT

108. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

109. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, performed pharmacovigilance, distributed, and sold the ParaGard IUD that was implanted into Plaintiff.

110. The ParaGard IUD implanted in Plaintiff contained a condition or conditions, which Defendants did not intend, at the time the ParaGard IUD left Defendants' control and possession.

111. Plaintiff and Plaintiffs' healthcare providers used the drug in a manner consistent with and reasonably foreseeable to Defendants.

112. As a result of this condition or these conditions, the product failed to perform as safely as the ordinary consumer would expect, causing injury, when used in a reasonably foreseeable manner.

113. ParaGard IUD was defectively and/or improperly manufactured, rendering it defective and unreasonably dangerous and hazardous to Plaintiff.

114. As a result of the manufacturing defects, ParaGard IUD creates risks to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of ParaGard IUD.

115. Defendants have intentionally and recklessly manufactured ParaGard IUD with wanton and willful disregard for the rights and health of Plaintiff and others, and with malice, placing their economic interests above the health and safety of Plaintiff and others.

116. As a proximate result of Defendants' manufacture of ParaGard IUD, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages.

117. Cooper Defendants are also liable as successors in interest under the any other state or federal successor-in-interest acts or statutes, and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory damages, punitive damages, and costs in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT IV – STRICT LIABILITY FAILURE TO WARN

118. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

119. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold ParaGard IUD, including the one implanted in Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the drug to consumers or persons responsible for consumers.

120. At the time Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold ParaGard IUD into the stream of commerce, Defendants knew or should have known that the drug presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use.

121. Specifically, Defendants knew or should have known that ParaGard IUD posed a significant risk that one of the arms of the drug could break upon removal, resulting in significant injuries.

122. Defendants had a duty to warn of the risk of harm associated with the use of the drug and to provide adequate warnings concerning the risk the drug could break upon removal, even if implanted properly and even if the drug remained properly in place.

123. Cooper Defendants had a continuing duty to warn Plaintiff, Plaintiff's physician, and/or the medical community of the potential for breakage at the arm(s) upon removal upon their acquisition of ParaGard IUD in September 2017.

124. Defendants failed to properly and adequately warn and instruct Plaintiff and her healthcare providers with regard to the inadequate research and testing of ParaGard IUD, and the complete lack of a safe, effective procedure for removal of ParaGard IUD.

125. The risks associated with ParaGard IUD are of such a nature that healthcare providers and users could not have recognized the potential harm.

126. ParaGard IUD was defective and unreasonably dangerous at the time of its release into the stream of commerce due to the inadequate warnings, labeling, and/or instructions accompanying the product including, but not limited to, the implantation and subsequent removal of ParaGard IUD.

127. The ParaGard IUD, when implanted in Plaintiff, was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed, and sold by Defendants.

128. Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of Plaintiff.

129. As a proximate result of Defendants' design, manufacture, marketing, sale, and/or distribution of ParaGard IUD, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, loss of comfort, and economic damages.

130. Cooper Defendants are also liable as successors in interest under any other state or federal successor-in-interest acts or statutes, and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory damages, punitive damages, and costs in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT V – COMMON LAW FRAUD

131. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

132. Defendants have falsely and fraudulently represented and continue to represent to the medical and healthcare community, Plaintiff and her physicians, and/or the public that ParaGard IUD had been appropriately tested and was found to be safe and effective.

133. The representations made by Defendants were, in fact, false. When Defendants made their representations, they knew and/or had reason to know that those representations were false, and they willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of ParaGard IUD.

134. These representations were made by Defendants with the intent of defrauding and deceiving the medical community, Plaintiff, and the public, and also inducing the medical community, Plaintiff, Plaintiff's physicians, and/or the public to recommend, prescribe, dispense, and purchase ParaGard IUD for use as a form of long-term birth control, all of which evidenced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of Plaintiff.

135. In representations to Plaintiff and/or to her healthcare providers, Defendants fraudulently concealed and intentionally omitted the following material information:

- a. That ParaGard IUD was not as safe as other products and procedures available to aid in the long-term prevention of pregnancy;
- b. That the risk of adverse events with ParaGard IUD was higher than with other products and procedures available for birth control;
- c. That ParaGard IUD was not adequately tested;
- d. That the limited clinical testing for ParaGard IUD revealed a higher risk of adverse events, above and beyond those associated with other products and procedures available for birth control;
- e. That Defendants deliberately failed to follow up on the adverse results from clinical studies and/or formal and informal reports from physicians and/or other healthcare providers and either ignored, concealed, and/or misrepresented those findings;
- f. That Defendants were aware of dangers in ParaGard IUD in addition to and above and beyond those associated with other products and procedures available for birth control;
- g. That ParaGard IUD was defective, and that it caused dangerous and adverse side effects, including but not limited to unacceptable incidence of breakage upon removal;
- h. That when ParaGard IUD needed to be removed, the removal procedure had a very high failure rate and/or needed to be performed repeatedly;
- i. That ParaGard IUD was manufactured negligently;

- j. That ParaGard IUD was manufactured defectively; and
- k. That ParaGard IUD was designed negligently and designed defectively.

136. Defendants were under a duty to disclose to Plaintiff and her physicians the defective nature of ParaGard IUD including, but not limited to, the risk of breakage prior to and upon removal, which could result in permanent injury.

137. Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects and, hence, cause dangerous injuries and damage to persons who used ParaGard IUD, such as Plaintiff.

138. Defendants' concealment and omissions of material facts concerning the safety of ParaGard IUD were made purposefully, willfully, wantonly, and/or recklessly to mislead Plaintiff, Plaintiff's physicians, surgeons, and healthcare providers and to induce them to purchase, prescribe, and/or dispense ParaGard IUD and/or to mislead them into reliance upon and cause them to use ParaGard IUD.

139. At the time these representations were made by Defendants, and at the time Plaintiff and/or her physicians used ParaGard IUD, Plaintiff and/or her physicians were unaware of the falsehood of these representations and reasonably believed them to be true.

140. Defendants knew and had reason to know that ParaGard IUD could and would cause severe and grievous personal injury to the users of the product and was inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

141. In reliance upon these false representations, Plaintiff and her physicians were induced to, and did use ParaGard IUD, thereby causing severe and permanent personal injuries and damages to Plaintiff. Defendants knew or had reason to know that Plaintiff and her physicians and other healthcare providers had no way to determine the truth behind Defendants' concealment

and omissions, which included material omissions of facts surrounding the use of ParaGard IUD as described in detail herein.

142. Plaintiff and her physicians reasonably relied on facts provided by Defendants, who foreseeably and purposefully suppressed and concealed facts that were critical to understanding the real dangers inherent in the use of ParaGard IUD.

143. Having knowledge based on Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assurances to Plaintiff, the public, and Plaintiff's healthcare providers and physicians, that ParaGard IUD was safe for use as a means of providing long-term birth control and was as safe or safer than other products and/or procedures available and/or on the market. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted, concealed, and suppressed the dissemination of certain results of testing and research to healthcare professionals, Plaintiff, her physicians, and the public at large.

144. Defendants had a duty—when disseminating information to the public—to disseminate truthful information, and a parallel duty not to deceive the public, Plaintiff, and/or her physicians.

145. The information distributed to the public, the medical community, Plaintiff, and her physicians by Defendants included, but was not limited to websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, professional literature, reports, press releases, advertising campaigns, television commercials, print advertisements, and/or other commercial media, and contained material representations which were false and misleading, as well as omissions and concealments of the truth about the dangers of the use of ParaGard IUD.

146. These representations, and others made by Defendants, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

147. Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of ParaGard IUD to Plaintiff, her physicians, and the public at large for the purpose of influencing the sales of products known to be dangerous and defective and/or not as safe as other alternatives.

148. At the time the representations were made, Plaintiff and her healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of ParaGard IUD.

149. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of Defendants, nor would Plaintiff with reasonable diligence have discovered the true facts about Defendants' misrepresentations at the time when the ParaGard IUD was surgically implanted into her.

150. Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of ParaGard IUD, neither Plaintiff nor her physician would not have purchased, used, or relied on Defendants' representations and omissions concerning ParaGard IUD.

151. As a proximate result of Defendants' design, manufacture, marketing, sale and/or distribution of ParaGard IUD, Plaintiff has been seriously injured and sustained severe and permanent injury, pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, loss of comfort, and economic damages.

152. Cooper Defendants are also liable as successors in interest under any other state or federal successor-in-interest acts or statutes, and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory damages, punitive damages, and costs in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT VI – NEGLIGENT MISREPRESENTATION

153. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

154. At relevant times, Defendants negligently provided Plaintiff, her healthcare providers, and the general medical community with false or incorrect information or omitted or failed to disclose material information concerning ParaGard IUD, including, but not limited to, misrepresentations regarding the safety of ParaGard IUD.

155. The information distributed by Defendants to the public, the medical community, Plaintiff, and her healthcare providers, including advertising campaigns, labeling materials, print advertisements, and commercial media, was false and misleading and contained omissions and concealment of truth about the dangers of ParaGard IUD.

156. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff and Plaintiff's health care providers; to falsely assure them of the quality of ParaGard IUD; and to induce the public and medical community, including Plaintiff and her healthcare providers, to request, recommend, prescribe, implant, purchase, and continue to use ParaGard IUD.

157. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, medical drug manufacturers, Plaintiff, her healthcare providers, and the public that ParaGard IUD had been tested and found to be safe and effective for long-term birth control.

158. The representations made by Defendants were, in fact, false. ParaGard IUD was not safe for human use in its intended and reasonably foreseeable manner. Use of ParaGard IUD is dangerous, as there is a risk that it may fracture upon removal causing significant injury.

159. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Plaintiff and Plaintiff's healthcare providers were induced to and did use ParaGard IUD, thereby causing Plaintiff to endure severe and permanent injuries.

160. Defendants knew and had reason to know that Plaintiff, Plaintiff's healthcare providers, and the general medical community did not have the ability to determine the true facts, which were intentionally and/or negligently concealed and misrepresented by Defendants.

161. Plaintiff and her healthcare providers would not have recommended and implanted ParaGard IUD had the true facts not been concealed by Defendants.

162. Defendants had sole access to the material facts concerning the defective nature of ParaGard IUD and its propensity to cause serious injuries.

163. At the time Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff was implanted with ParaGard IUD, Plaintiff and her healthcare providers were unaware of Defendants' negligent misrepresentations and omissions.

164. Defendants failed to exercise ordinary care in making representations concerning ParaGard IUD while they were involved in the drug's manufacture, sale, testing, quality assurance,

quality control, and distribution in interstate commerce because Defendants negligently misrepresented ParaGard IUD's high risk of unreasonable and dangerous adverse side effects.

165. Defendants breached their duty to Plaintiff, her physicians, and the medical and healthcare community by representing that ParaGard IUD has no serious side effects different from older generations of similar products or procedures.

166. Plaintiff and Plaintiff's healthcare providers reasonably relied upon the misrepresentations and omissions made by Defendants, where they concealed and misrepresented facts that were critical to understanding the true dangers inherent in the use of ParaGard IUD.

167. Plaintiff's and Plaintiff's healthcare providers' reliance on the foregoing misrepresentations and omissions was the direct and proximate cause of Plaintiff's injuries.

168. Defendants knew, and had reason to know, that ParaGard IUD had been insufficiently tested or had not been tested at all; that the products lacked adequate and accurate warnings; that they created a high risk, and/or higher than acceptable risk, and/or higher than reported risk that they represented a risk of adverse side effects, including pain and suffering, surgery to remove the product, and other severe and personal injuries, which are permanent and lasting in nature.

169. As a proximate result of Defendants' design, manufacture, marketing, sale, and/or distribution of ParaGard IUD, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, loss of comfort, and economic damages.

170. Cooper Defendants are also liable as successors in interest under any other state or federal successor-in-interest acts or statutes, and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory damages, punitive damages, and costs in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT VII – BREACH OF EXPRESS WARRANTY

171. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

172. At relevant times, Defendants intended that ParaGard IUD be used in the manner that Plaintiff used it and Defendants expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other treatments for long-term birth control, and that the products were adequately tested and fit for their intended use.

173. At relevant times, Defendants were aware that consumers, including Plaintiff, would use ParaGard IUD, which is to say that Plaintiff was a foreseeable user of ParaGard IUD.

174. Plaintiff and/or her implanting physicians were, at all relevant times, in privity with Defendants.

175. ParaGard IUD was expected to reach and did in fact reach its ultimate consumer, including Plaintiff and her implanting physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

176. Defendants breached various express warranties with respect to ParaGard IUD, including the following particulars:

- a. Defendants represented to Plaintiff and her physicians and healthcare providers through their labeling, advertising, marketing materials, detail persons, seminar

presentations, publications, notice letters, and regulatory submissions that ParaGard IUD was safe, and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using ParaGard IUD;

- b. Defendants represented to Plaintiff and her physicians and healthcare providers that ParaGard IUD was as safe and/or safer than other alternative procedures and drugs, and fraudulently concealed information that demonstrated that ParaGard IUD was not safer than alternatives available on the market; and
- c. Defendants represented to Plaintiff and her physicians and healthcare providers that ParaGard IUD was more efficacious than other alternatives and fraudulently concealed information regarding the true efficacy of the product.

177. In reliance upon Defendants' express warranties, Plaintiff was implanted with ParaGard IUD as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

178. At the time of making such express warranties, Defendants knew or should have known that ParaGard IUD does not conform to these express representations because ParaGard IUD was not safe and had numerous side effects, many of which Defendants did not accurately warn about, thus making ParaGard IUD unreasonably unsafe for its intended purpose.

179. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff and her physicians, relied upon the representations and warranties of Defendants in connection with the use, recommendation, description, and/or dispensing of ParaGard IUD.

180. Defendants breached their express warranties to Plaintiff in that ParaGard IUD was not of merchantable quality, safe, and/or fit for its intended uses, nor was it adequately tested.

181. As a proximate result of Defendants' design, manufacture, marketing, sale and/or distribution of ParaGard IUD, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, loss of comfort, and economic damages.

182. Cooper Defendants are also liable as successors in interest under any other state or federal successor-in-interest acts or statutes, and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory damages, punitive damages, and costs in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT VIII – BREACH OF IMPLIED WARRANTY

183. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

184. At relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold ParaGard IUD.

185. At relevant times, Defendants intended that ParaGard IUD be implanted for the purposes, and in the manner, that Plaintiff or her physicians or surgeons used it, and Defendants impliedly warranted each ParaGard IUD to be of merchantable quality, safe and fit for such use, and to have been adequately tested.

186. Defendants were aware that consumers, including Plaintiff or her physicians or surgeons, would implant ParaGard IUD in the manner described by the instructions for use and that Plaintiff was the foreseeable user of ParaGard IUD.

187. Plaintiff and/or her physicians and surgeons were at all relevant times in privity with Defendants.

188. Defendants' ParaGard IUD was expected to reach and did in fact reach consumers, including Plaintiff and/or her physicians and surgeons, without substantial change in the condition in which they were manufactured and sold by Defendants.

189. Defendants breached various implied warranties with respect to ParaGard IUD, including the following particulars:

- a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, medical literature, and regulatory submissions that ParaGard IUD was safe, and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using ParaGard IUD;
- b. Defendants represented that ParaGard IUD was safe and/or safer than other alternative drugs or procedures and fraudulently concealed information that demonstrated that ParaGard IUD was not as safe or safer than alternatives available on the market; and
- c. Defendants represented that ParaGard IUD was more efficacious than other alternative treatments and fraudulently concealed information regarding the true efficacy of ParaGard IUD.

190. In reliance upon Defendants' implied warranties, Plaintiff and/or her implanting physicians and surgeons used ParaGard IUD as prescribed in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

191. Defendants breached their implied warranties to Plaintiff and/or her implanting physicians and surgeons in that ParaGard IUD was not of merchantable quality, safe, and fit for its intended use, or adequately tested, in violation of common law principles.

192. As a proximate result of Defendants' design, manufacture, marketing, sale and/or distribution of ParaGard IUD, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, loss of comfort, and economic damages.

193. Cooper Defendants are also liable as successors in interest under any other state or federal successor-in-interest acts or statutes, and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory damages, punitive damages, and costs in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT IX – VIOLATION OF CONSUMER PROTECTION LAWS

194. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

195. Plaintiff purchased and used ParaGard IUD primarily for personal use, thereby suffering ascertainable losses from Defendants' actions in violation of consumer protection laws.

196. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff and her physicians would not have purchased and/or paid for ParaGard IUD and would not have incurred related medical costs and injury.

197. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for ParaGard IUD that was implanted into her and that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

198. Unfair methods of competition or deceptive acts or practices that were proscribed by law include the following:

- a. Representing that goods or services have characteristics, ingredients, uses, benefits, or quantities that they do not have;
- b. Advertising goods or services with the intent not to sell them as advertised; and
- c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion and/or misunderstanding.

199. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians, and consumers, including Plaintiff and her physicians, was to create demand for and promote the sale of ParaGard IUD. Each aspect of Defendants' conduct combined to artificially create sales of ParaGard IUD.

200. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of ParaGard IUD.

201. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for ParaGard IUD and would not have incurred related medical costs.

202. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians, and consumers, including Plaintiff and her physicians, constituted unfair and deceptive acts and trade practices in violation of state and federal consumer protection statutes.

203. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive, or fraudulent acts or trade practices in violation of state and federal consumer protection statutes, including but not limited to the Colorado Consumer Protection Act, Colo. Rev. Stat. §§6-1-101 et seq & Washington Unfair Business Practices - Consumer Protection, Wash. Rev. Code §19.86 et seq.

204. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the statute listed above to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising. Defendants are the suppliers, manufacturers, advertisers, and sellers who are subject to liability under such legislation for unfair, deceptive, fraudulent, and unconscionable consumer sales practices.

205. Defendants engaged in fraudulent behavior regarding the transfer and/or sale of assets to Cooper Defendants in 2017. Cooper Defendants knew or should have reasonably known that the transfer of assets was done in a manner consistent with and in an effort to deceive potential creditors.

206. Pursuant to the terms of the asset purchase agreement, Teva Women's Health, Inc., claims to maintain liability for all ParaGard IUD placed prior to the execution of the asset purchase agreement in September 2017. However, Teva Women's Health, Inc., converted to Teva Women's Health, LLC and sold all of its assets.

207. Cooper Defendants knew or reasonably should have known that Teva Defendants converted Teva Women's Health, Inc., into Teva Women's Health, LLC after selling or moving all assets from Teva Women's Health, Inc.

208. Therefore, Cooper Defendants knew or reasonably should have known that Teva Defendants' shuffling of assets and subsequent conversions were done to thwart potential creditors in violation of Colorado Consumer Protection Act, Colo. Rev. Stat. §§6-1-101 et seq & Washington Unfair Business Practices - Consumer Protection, Wash. Rev. Code §19.86 et seq and federal consumer protection laws.

209. Defendants violated the statutes that were enacted to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising by knowingly and falsely representing that ParaGard IUD was fit to be used for the purpose for which it was intended, when in fact it was defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials and product labeling.

210. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising.

211. Defendants had actual knowledge of the defective and dangerous condition of ParaGard IUD and failed to take any action to cure such defective and dangerous condition.

212. Plaintiff and her implanting physicians and surgeons relied upon Defendants' misrepresentations and omissions in determining which product to use and/or procedure to undergo and/or perform.

213. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians, and consumers constitute unfair and deceptive acts and practices.

214. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

215. As a proximate result of Defendants' design, manufacture, marketing, sale and/or distribution of ParaGard IUD, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, loss of comfort, and economic damages.

216. Cooper Defendants are also liable as successors in interest under any other state or federal successor-in-interest acts or statutes,; and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory damages, punitive damages, and costs in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT X – GROSS NEGLIGENCE

217. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

218. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law, for the imposition of exemplary damages, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff; or, when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved

but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included material representations that were false, with Defendants knowing that they were false or with reckless disregard as to the truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff.

219. Plaintiff and her physicians relied on the representations of Defendants and suffered injury as a proximate result of this reliance.

220. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

221. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff. In that regard, Plaintiff will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

222. Cooper Defendants are also liable as successors in interest under any other state or federal successor-in-interest acts or statutes, and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory damages, punitive damages, and costs in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT XI – PUNITIVE DAMAGES

223. Plaintiff incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

224. At times material hereto, Defendants knew or should have known that their ParaGard IUD, as designed, manufactured, assembled, sold, and/or distributed, was inherently dangerous.

225. At times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of their ParaGard IUD.

226. Defendants' misrepresentations included knowingly withholding material information from the public and consumers alike, including Plaintiff, concerning the safety of ParaGard IUD.

227. At times material hereto, Defendants knew and recklessly disregarded the fact that their ParaGard IUD could cause serious, disabling, and permanent injuries to individuals such as Plaintiff.

228. Notwithstanding the foregoing, Defendants continued to aggressively market and promote their ParaGard IUD without disclosing the risks.

229. As a proximate result of Defendants' willful, wanton, careless, reckless, conscious, and deliberate disregard for the rights and safety of their consumers, Plaintiff suffered severe and permanent physical and emotional injuries, endured pain and suffering, and has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future.

230. Defendants' aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton, and deliberate disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

231. Cooper Defendants are liable as successors in interest under any other state or federal successor-in-interest acts or statutes, and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory damages, punitive damages, and costs in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT XII LOSS OF CONSORTIUM

232. Plaintiff incorporates the allegations in all prior paragraphs and further alleges as follows:

233. At all times material, Plaintiff, Leigh Brooke Goldberg, was married to Plaintiff, Adam Matthew Balest. As a result of the injuries and damages sustained by Leigh Brooke Goldberg, Adam Mathew Balest has suffered the loss of care, comfort, society, and affections from Leigh Brooke Goldberg.

234. Cooper Defendants are liable as successors in interest under any other state or federal successor-in-interest acts or statutes, and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory damages, punitive damages, and costs in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

PRAAYER FOR RELIEF

So far as the law and this Court allows, Plaintiffs demand judgment against each Defendant on each count as follows:

- a. All available compensatory damages for the described losses with respect to each cause of action;
- b. Past and future medical expenses, as well as the cost associated with past and future life care;
- c. Past and future lost wages and loss of earning capacity;
- d. Past and future emotional distress;
- e. Consequential damages;
- f. All available noneconomic damages, including, without limitation, pain, suffering, and loss of enjoyment of life;
- g. Punitive damages with respect to each cause of action;
- h. Reasonable attorneys' fees where recoverable;
- i. Costs of this action;
- j. Pre-judgment and all other interest recoverable; and
- k. Such other additional, further, and general relief as Plaintiff may be entitled to in law or in equity as justice so requires.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury as to all issues.

DATED this 3rd day of May, 2021.

THE LEDGER LAW FIRM, P.S.



David L. Mann, WSBA #50577
Attorney for Plaintiff